Appln No.: 09/780,060
Amendment Dated: June 2, 2004
Reply to Office Action of August 21, 2002

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A skin barrier replacement composition comprising an aqueous formulation of at least ~~two~~ three lipids in a non-crystalline phase lamellar array which adopt a crystalline lamellar phase upon application to mammalian skin, wherein the at least three lipids comprise a ceramide, a saturated fatty acid and cholesterol, and wherein the composition comprises bovine brain ceramide or ceramide 2 as the ceramide, palmitic acid as the saturated fatty acid and cholesterol in ratios by mol of from 1-5:1-5:1-5, respectively.

2-5 (cancelled)

6. (currently amended) The composition of claim ~~2~~ 1, wherein said aqueous formulation of lipids consists of multilamellar vesicle or large unilamellar vesicle liposomes or a mixture thereof.

7. (original) The composition of claim 6, wherein said liposomes have a median diameter of 15 to 1500 nm.

8. (currently amended) The composition of claim ~~2~~ 1, wherein said crystalline lamellar phase forms after penetration into the stratum corneum of the skin.

9. (currently amended) The composition of claim ~~2~~ 1, wherein said non-crystalline phase is a liquid crystal

10. (currently amended) A skin barrier replacement composition comprising an aqueous

formulation of at least three lipids in a non-crystalline phase lamellar array which adopt a crystalline lamellar phase upon application to mammalian skin ~~The composition of claim 2~~, wherein said non-crystalline phase is a gel

11. (currently amended) A skin barrier replacement composition comprising an aqueous formulation of at least three lipids in a non-crystalline phase lamellar array which adopt a crystalline lamellar phase upon application to mammalian skin, ~~The composition of claim 2,~~ wherein said non-crystalline phase is a complex phase.

12. (original) The composition of claim 11, wherein said complex phase is a combination of phases selected from among gel, liquid crystal and crystalline phases, wherein the crystalline phase does not exceed 30% of the lipids by mass.

13. (currently amended) A skin barrier replacement composition comprising an aqueous formulation of at least three lipids in a non-crystalline phase lamellar array which adopt a crystalline lamellar phase upon application to mammalian skin, ~~The composition of claim 2,~~ wherein said crystalline phase induced upon application to the skin is greater than 70% crystalline as measured by deuterated fatty acid mobility in NMR.

14. (currently amended) The composition of claim ~~2~~ 1, wherein the aqueous formulation contains no organic solvent or alcohol.

15. (currently amended) The composition of claim ~~2~~ 1, wherein the aqueous formulation is sufficiently polar to support multilamellar vesicle formation

16. (currently amended) The composition of claim ~~2~~ 1, wherein the composition contains no squalene.

17. (currently amended) The composition of claim ~~2~~ 1, wherein the lipid mixture contains no phospholipid or glucosylceramide

18. (currently amended) The composition of claim ~~2~~ 1, wherein the lipid mixture contains no unsaturated fatty acid.

19. (currently amended) The composition of claim ~~2~~ 1, wherein the lipid mixture contains no surfactant.

20-21. (canceled)

22. (currently amended) A method of recovering or improving a mammalian skin permeability barrier comprising

(a) administering to the skin a composition of lipids comprising an aqueous formulation of at least ~~two~~ three lipids in a non-crystalline phase lamellar array, wherein the at least three lipids comprise a ceramide, a saturated fatty acid and cholesterol, and wherein the composition comprises bovine brain ceramide or ceramide 2 as the ceramide, palmitic acid as the saturated fatty acid and cholesterol in ratios by mol of from 1-5:1-5:1-5, respectively; and

(b) allowing said composition to dry, wherein said dried composition adopts a crystalline lamellar phase after said administering to the skin.

23-26. (cancelled)

27. (currently amended) The method of claim ~~23~~ 22, wherein said aqueous formulation of lipids consists of MLV liposomes.

28. (original) The method of claim 27, wherein said MLVs have a median diameter of 100 to

1500 nm.

29. (currently amended) The method of claim ~~24~~ 22, wherein said crystalline lamellar phase forms after penetration into the stratum corneum of the skin.

30. (currently amended) The method of claim ~~24~~ 22, wherein said non-crystalline phase is a liquid crystal.

31. (currently amended) The method of claim ~~24~~ 22, wherein said non-crystalline phase is a gel

32. (currently amended) The method of claim ~~24~~ 22, wherein said non-crystalline phase is a complex phase.

33. (original) The method of claim 32, wherein said complex phase is a combination of phases selected from among gel, liquid crystal and crystalline phases, wherein the crystalline phase does not exceed 25% of the lipids by mass.

34. (currently amended) The method of claim ~~24~~ 22, wherein said crystalline phase induced upon application to the skin is greater than 70% crystalline as measured by deuterated fatty acid mobility in NMR.

35. (currently amended) The method of claim ~~24~~ 22, wherein the aqueous formulation contains no organic solvent or alcohol.

36. (cancelled)

37. (currently amended) The method of claim ~~24~~ 22, wherein the composition contains no squalene.

38. (currently amended) The method of claim ~~24~~ 22, wherein the lipid mixture contains no phospholipid.

39. (currently amended) The method of claim ~~24~~ 22, wherein the lipid mixture contains no unsaturated fatty acid.

40. (currently amended) A pharmaceutical preparation comprising a therapeutic compound in an aqueous formulation of at least three lipids in a non-crystalline phase lamellar array which adopt a crystalline lamellar phase upon application to mammalian skin, wherein the at least three lipids comprise a ceramide, a saturated fatty acid and cholesterol, and wherein the composition comprises bovine brain ceramide or ceramide 2 as the ceramide, palmitic acid as the saturated fatty acid and cholesterol in ratios by mol of from 1-5:1-5:1-5, respectively and further comprising a therapeutic or bioactive agent.